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APPLICATOR FOR SURGICAL CLIPS

Technical Field

The present application relates to applicators for surgical clips and more particularly to applicators for ligation clips.

Background of Related Art

Certain known applicators for clips use a push rod and associated link mechanism to cause rotation of an articulated jaw to produce compression forces on a clip and to thereby compress the clip causing it to close preferably with a latching action. The compression forces on the relatively slender central rod produce the risk of buckling with consequent lost motion. In addition, the mechanical force from the link causes radial reaction forces and consequent friction at the interface between the push rod and the outer tube.

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For known applicators, this creates a requirement that the applicator must be made from high grade components which will withstand such forces and be able to perform many clip closure operations.

20 Additionally such designs with rotational closure forces usually require a clip to be inserted into the jaws of the applicator prior to clip closure. Thus, the applicator can only apply one clip at a time.

EP-A-820725 discloses a surgical instrument for performing anastomosis of tubular body tissues and comprises inner and outer members which move relative to each other to compress a clip by compressing a force on the clip in

a direction parallel to the relative movement direction of the inner and outer members.

EP-A-916309 discloses with particular relevance to Figure 8A an applicator
5 for a clip and compresses inner and outer members which can move relative to each other, the clip being positioned between jaw members attached to the inner and outer members and the clip being closed by relative movement the force applied to the clip being in parallel with the relative movement direction of the inner and outer members.

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WO-A-9108708 discloses a suture tie device system which effects closure of a suture tie by relative movements between inner and outer members pressure being exerted on the suture tie in a direction parallel to the relative direction of movement of the members.

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It is an object of the present invention to provide an applicator for surgical clips which is of a simpler, more robust design to such known applicators.

It is a further object of the preferred embodiment of the present invention to
20 provide an applicator which can store and be used to apply a multiplicity of clips.

Such an applicator may be partially or completely disposable.

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Summary

The present invention therefore provides an applicator for surgical clips having upper and lower jaw members with co-operating locking means when

in a closed position, the applicator comprising: a handle; a barrel portion constructed and arranged to be operatively attached to the handle, the barrel portion including an inner member and an outer member, the inner and outer members being slidable relative to each other, the inner member and the
5 outer member further being shaped to retain at least one surgical clip, and including co-operating distal surfaces; wherein as the handle operates to slide the inner member relative to the outer member the surgical clip is forced from an open to a closed position by a compressed force, orthogonal to the direction of sliding, between the outer member and the inner member, the
10 force being sufficient to compress the upper jaw member and to cause the upper jaw member to lock into engagement with the lower jaw member.

Preferably, the outer member comprises an elongate tube shaped at an end distal from the handle to retain the surgical clip.

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Preferably, the shape of the distal end of the outer member comprises an angled sloping platform constructed and arranged to support the surgical clip, the sloping platform also comprising a raised flange forming a stop member for the surgical clips.

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Preferably, the inner member comprises an elongate inner member, the elongate inner member including a storage member to store the multiplicity of surgical clips.

25 Preferably, the applicator includes an inducing member to index the multiplicity of surgical clips down the elongate inner member.

The elongate inner member preferably includes a stop member operable to provide opposing mechanical forces to oppose the force on a surgical clip by the outer member to create closure of the clip.

- 5 The present invention also provides a magazine storage system for an applicator for surgical clips having an upper jaw member and a lower jaw member with co-operating locking means when in a closed position, the magazine storage system comprising: a barrel portion including an attachment member at a proximal end constructed and arranged to attach the barrel portion to a handle, the barrel portion further comprising; a plurality of surgical clips stored in a single column array within the barrel portion; an inner member and an outer member, slideable relative to each other, the inner and outer members further being shaped to retain the plurality of surgical clips, and the inner and outer member each having at a distal end co-
10 operating surfaces shaped to cause each of the surgical clips to be forced from an open to a closed position when the inner and outer members are slid relative to each other the sliding motion creating a compressed force, orthogonal to the direction of sliding, between the outer member and the inner member sufficient to compress the upper jaw member of each surgical
15 clip and to cause the upper jaw member to lock into engagement with the lower jaw member.
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Preferably, the magazine storage system includes a biasing member positioned within the inner member, the biasing member being operative to urge the plurality of surgical clips from the proximal to the distal end of the barrel portion.
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The outer member preferably comprises at the distal end a ledge shaped stop member to arrest movement of the plurality of surgical clips, the ledge shaped stop member providing leverage to effect closure of the clip when the outer member is moved relative to the inner member.

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Preferably, a ratchet stop member is provided in the inner member, the ratchet stop member being positioned between the biasing or spring member and the plurality of surgical clips. the ratchet stop member being moveable by the spring member in a direction from the proximal to the distal end of the
10 barrel portion, the ratchet stop member being co-operative with a corresponding ratchet member on the inner member to prevent movement in the opposite direction.

Brief Description of the Drawings

15 It should be understood that the drawings are provided for the purpose of illustration only and are not intended to define the limits of the invention. The foregoing and other objects and advantages of the embodiments described herein will become apparent with reference to the following detailed description when taken in conjunction with the accompanying drawings in
20 which:

Figure 1 shows the applicator of the present invention in side elevation;

25 Figure 2 shows the applicator of Figure 1 in cross-sectional elevation;

Figure 3 shows the applicator of Figure 2 in plan view;

Figure 4 shows the barrel portion of the applicator of Figure 2 in plan view;

5 Figure 5 shows the barrel portion of the applicator of Figure 2 in cross-sectional elevation;

Figure 6 shows the handle portion of the applicator of Figure 2 in cross-sectional side elevation;

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Figure 7 shows the handle portion of Figure 6 in end view;

Figure 8 shows the handle section of Figure 6 in cross-section along line A¹-A¹;

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Figure 9 shows in detail a portion of the barrel section of the applicator in greater detail;

Figure 10 shows the barrel of Figure 9 in end view;

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Figure 11 shows the barrel portion of the applicator in an exploded view;

Figure 12 shows the handle portion of the applicator in partial cross-section showing the spring actuated first and second levers; and

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Figure 13 shows schematically a perspective view of the barrel assembly.

Detailed Description of the Illustrative Embodiments

- 5 With reference now to the drawings, Figure 1 shows a surgical clip applicator 10 according to the present invention. The applicator 10 includes a handle 12 and a barrel portion 14. Within the handle 12 two levers 16 and 18 are located. The lever 16 in operation indexes the clips down the barrel portion 14, as explained hereinafter, and the lever 18 provides the operating force to
10 effect closure of the clips.

The mechanical detail of the handle 12 and the barrel portion 14 are shown in Figure 2. The lever 16 is shown in two positions 16 and 16'. In position 16', the clips 140 in barrel portion 14 are fed forwardly as will be explained
15 hereinafter. The lever 18 is also shown in two positions, 18 and 18'. In position 18', the lever 18 is operative to provide the pressure to close one of the clips 140.

The lever 16 is also operative in combination with biasing member or spring
20 142 (shown only diagrammatically) to move a stop member 144 along barrel portion 14. This stop member provides a stop to enable each clip 140 to be subjected to closing pressure as now described. The stop member 144 preferably is provided with a ratchet member 146 to prevent rearward movement whilst allowing forward movement in the direction of arrow 148.

At the end of barrel portion 14, an operating tip portion 1400 is formed. The operating tip portion 1400 preferably comprises an inclined lower platform 1402 shown in greater detail in Figure 9.

- 5 In operation, the lever 18 shown moved to position 18' moves the inner member 143 in the direction of arrow 1404 (Fig. 9). The clips 140 are closed by compression between the lower platform 1402 and the inner member end portion 1406, as shown in the segmental drawing in Figure 9.
- 10 The barrel portion 14 may be disposable and may be loaded with a multiplicity of clips, e.g. 2, 4, 6, 8 or 12, dependent on the operation being performed.

The barrel portion 14 has a diameter of H and as can be seen by the circle, 15 the clip when it emerges from the barrel into the end section 1402 has a jaw width W. This defines the width to which the jaw will open, taking into account the silicon rubber lining 1403. It may be seen that with this design of applicator and clip the jaw opening W is substantially larger than the diameter H thereby providing a wide capture width.

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With reference to Figures 4 and 5, the barrel portion 14 is shown in isolation from the handle 12. The handle lever 18 operates on shoulder 1410 to move inner member 143.

25 Handle 12 is shown in greater detail in Figures 6 to 8. The handle 12 may be disposable or may be reusable but preferably the barrel portion 14 is disposable and is supplied in a "sterilised form for each operation".

The barrel portion 14 is preferably circular in cross-section. The barrel portion 14 may be rotated to always be in a suitable orientation by the surgeon so that the handle 12 may always be held in a suitable position
5 allowing easy operation of lever 18.

With reference now to Figure 11, a preferred example of the barrel portion 14 is shown in exploded form. The clips 140 are not shown for ease of illustration but will normally be present as shown in previous figures. The
10 barrel portion 14 comprises an outer member 141 which comprises a generally circular cross-section tube with the end operational portion 1402 formed integrally at the distal end. Within the outer member 141 is the inner member 143 which also forms a magazine to house the clips 140. The inner member 143 is preferably formed integrally with the operational closure
15 member 1406. Within the inner member 143 the biasing member or spring 142 operates against the stop member 144, which in this case comprises a push rod 1440 within a small bore tube 1442. The outer member 141 and inner member 143 are located in the shoulder section 1410 which as described is replaceably locatable in the handle 18. The barrel portion is
20 spring loaded into the handle by spring means 1411 to ensure correct fitment.

Figure 12 shows the handle 12 of the applicator in partial cross-section illustrating the spring mechanisms. Parts are numbered as in previous figures. The main operating lever 18 is spring loaded by a spring 182 to its
25 non-operating position as shown. The second operating lever 16 is spring loaded by a spring 162 acting against flange member 164 to return lever 16 to its non-operating position.

Since all barrel portion members are preferably of circular cross-section they are located in handle 12 in a manner enabling the barrel portion 14 to be rotated with respect to handle 12 allowing the surgeon to selectively orientate
5 the barrel portion and hence the clip closure with respect to the handle.

With reference now to Figure 13 the barrel portion 14 is shown schematically. This figure illustrates two features. The first feature is the change from inner member 143 to a round section. The other is the optional
10 clip retention feature 1405, 1407 which provides a side grip on the clip to grip the clip by its lower jaw silicone rubber lining.

The superior features of the new applicator design are now summarised.

- 15 1. The axial sliding of two members 141; 143 of the shaft is used as a reliable and simple way to transmit actuation force from the operator interface to the clip closing jaws.
- 20 2. The outer member 141 extends to form the clip tray 1402 and jaw forms the tension link. The inner member 143 is the compression link exploiting the superior compression stability of this member.
- 25 3. Within the central core (channel) multiple clips 140 are stored for consecutive advancing and closing.

The system depends on the relationship between the profile of the upper jaw of the clip, the angle of the end operational portion 1402 of

the outer member 141, and the profile at the end of the channel 1406 during sliding movement of the two latter items.

5 An optional clip retention device 1405, 1407 is included in the clip jaw which preferably grips on the silicone liner at the base of the clip so loss of control is avoided during surgery, but ensures easy release after closure.

10 Clip indexing along the channel utilises a one way frictional moving buffer and constant force spring (like a staple gun).

Clip closure is actuated by the large (major) trigger 18 in the handle and clip indexing by the smaller (minor) trigger 16 in the handle.

15 The major trigger action and stroke on the applicator is achieved as a result of a large finger bar 18 on the underside of the pistol grip handle to avoid pressure on one finger when closing clips.

20 Springs in the handle assembly and clip magazine assembly return the components to the neutral position after clip closure and in readiness for the next clip to be indexed in the clip jaw or tray.

A single clip system could operate on the same basis but without a long channel to house the clips.

25 The handle shape is optimised in relation to ergonomic data.

The clip magazine may be disposable.

5 The sliding tube technique is less likely to cause high localised stress in the tissue due to concentration of deformation at the centre of the upper jaw of the clip.

The design principle of the magazine feed applicator offer the following features.

10 1. A disposable multi clip magazine.

2. Disposable barrel portion with clip closure functioning at surgical end but moving in a linear plane rather than through an arc.

15 3. The barrel and magazine indexed radially so the surgeon can adjust the angle of the jaws in relation to the hand position without changing angle of arm or conversely, if the surgeon has to change his arm position to avoid the patient, then he can still adjust the barrel portion to the correct working position.

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4. A reusable handle with primary trigger for closing the clip, secondary trigger for both moving the clips in the barrel.

25 5. The handle/barrel arrangement and clip closure mechanism allows the surgeon's hand to remain in constant relationship with the operation of the clip for accurate surgical procedures.

6. The applicator is pre-set at manufacture which avoids calibration and maintenance. Magazines with 2, 4, 6, 12 clips could be preloaded and sold as sterile packs for insertion into common handles in the operating theatre.

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7. The principle could be used for the Filshie clip (British Patent No 2177748) with magazines suitably matched to clip size and common handle. In a preferred embodiment, different colour/identity marking on the magazines would be used to distinguish ligation clips from Filshie clips.

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8. The elimination of calibration will reduce the cost of maintenance.

9. The outer portion of the magazine acts as the tension link and the inner channel as the compression one, so that a clip is held in the clip tray at an angle to the line of force in order to close a clip over a vessel.

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10. Clips in the magazine, but not in a position to be closed are preferably retained by small escapement spring in the outer tube and a slot in the channel acting to restrain the clips.

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11. In a preferred embodiment, a snap action (i.e., an audible noise) alerts the surgeon to closure of clips. This avoids excessive pressure on the main trigger mechanism.

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A general description of the applicator system and method of operation is as follows:

The clip application system consists of a preferably "pistol" shaped handle 12 and a barrel portion 14 that contains the clip magazine. The magazine barrel sterile packs are preferably text marked and colour coded to identify the type and number of clips that they contain. The barrels themselves are colour coded in the same way. These magazine barrels may repeatedly be loaded with single clips, once the internal magazine is exhausted but are intended to be disposable at the conclusion of each procedure. Barrels for hand loading of single clips may be sterilised for repeated use.

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The hand grip or handle 12 is common to all barrel portions and may be sterilised for repeated use. The hand grip incorporates all controls and requires no calibration or adjustment when changing the type of barrel. The operable controls are: a primary trigger which closes and latches clips; a secondary trigger which may prevent inadvertent latching of clips and feeds successive clips into the jaw for use; twin buttons 122 (only one shown in Fig 1) that release the barrel portion from the hand grip. In addition, a textured grip 1469 (Fig 13) on the rear end of the barrel portion allows this to be rotated to any convenient orientation relative to the handle.

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The handle may be held in either hand, stabilised by the thumb. The secondary trigger 16 is operated by the index finger and the remaining fingers are used to squeeze the trigger 18 . The retainer release buttons 122 are operated by squeezing between the thumb and index finger. All controls require force to be applied in one direction only and return to their normal positions under the action of internal springs.

The principal actions required when using of the applicator system are listed below and described in the following paragraphs.

- Loading pistol with sterile barrel portions
- 5 ▪ Loading first clip to jaw
- Closing/opening clip
- Latching clip
- Releasing latched clip and loading next clip
- Ejecting used barrel from pistol

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Loading pistol with sterile barrel portions

Barrel portions (14) are supplied completely enclosed in an individual sterile pack (not shown). If the cylindrical portion of the barrel is gripped in either hand, the part of the pack covering the end to be inserted into the handle may 15 be torn and removed. If the handle is taken up, in either hand, the exposed part of the barrel portion may be fed into the nose of the handle. When inserted approximately 20mm, a resistance will be felt. Increased insertion force will cause the sprung retainer to retract, allowing full insertion of the barrel portion. When the barrel portion is fully inserted, the retainer will 20 engage with an audible click. Proper engagement should be tested by pulling the barrel portion 14 away from the handle 12. The barrel portion 14 must be retained but be free to revolve within the handle 12. The assembled handle and barrel portion may now be laid down with the sterile sheath in place on the barrel portion or this may be removed for surgical use and 25 insertion into a cannula.

Loading first clip to jaw

The handle 12 is held in either hand, the index finger is placed on the secondary trigger 16 and the remaining fingers are relaxed. The secondary trigger is drawn back to the full extent of travel and then released. A clip 140 will appear at the nose of the barrel portion and will be carried forward
5 into the jaw. When the secondary trigger is released, the clip will be open.

Closing/opening clip

The clip 140 may be progressively closed and latched in one continuous action or, if desired, the motion of the applicator may be limited to allow
10 closing the clip but preventing final latching. Holding the handle in either hand, the primary trigger is squeezed. After a short initial travel, the clip will commence closing and further movement of the trigger to the limit of travel will close and then latch the clip. If the motion is ceased at any point up to latching of the clip and pressure on the trigger is relaxed, the clip will
15 return to the fully open position. The clip is positively retained in the jaw throughout these actions.

If it is desired to positively prevent inadvertent overtravel and consequent latching of the clip, the following procedure is required. With the handle in
20 either hand and the trigger 18 in relaxed position, the trigger 16 is lightly drawn back. An initial rotational movement will be perceived after which increased resistance will be felt. While maintaining the secondary trigger in this position, the trigger 18 is drawn back. The clip will close as before but further travel beyond the closed position will be prevented as long as the
25 secondary trigger is engaged. When it is desired to allow further travel of the trigger 18 to latch the clip, the trigger 16 is released.

Latching clip

- The clip may be latched by squeezing the trigger 18 to the full extent of travel. As explained above, this may be done directly from the initial position, clip open, or from the intermediate position, clip depressed. In all 5 cases, it is important that the trigger 18 be squeezed to the fullest extent of travel once it is desired to latch the clip. After completion of latching, the trigger 18 is released and will return to the relaxed position. The clip will be retained in the jaw.
- 10 With reference to Figure 13, the shaped portion of the inner tube 1406 is preferably moved towards the end stop 1402 to effect closure of the clip as shown in Figure 9. This provides the relatively smooth closure action of the clip resulting in uniform distribution of pressure across the tissue being occluded by the clip.

15 When the clip has been positioned at the end of the barrel portion in a position to be actuated, the portion 1406 of the inner member 143 contacts the upper jaw of the clip near to the hinge of the clip which will be opened by the pressure of the silicone lining of the clip. Thus, the portion 1406 acts as 20 a stop to prevent the clips from falling out whilst also ensuring maximum occlusion capacity as can be seen in Figure 9.

Releasing latched clip and loading next clip

When it is desired to release the latched clip, the secondary trigger is drawn back, through the initial rotational movement and into the sliding movement. 25 After a small amount of movement, the clip will be free to leave the jaw. If it is required to engage the next clip, the secondary trigger 16 should be

drawn back to the full extent of travel and released. A clip will appear at the nose of the barrel portion and will be fed forward into the clip tray 1402. When all triggers are released, the clip will be open.

5 Ejecting used barrel portion from handle

To remove the barrel portion from the handle manually, take up the handle with the thumb and forefinger placed either side of the body, upon the release buttons 122. If these buttons are squeezed, the barrel portion may be withdrawn from the handle. To eject the barrel portion from the handle
10 without having to touch the barrel portion, the handle is taken in the normal hold and the primary trigger is drawn back to the full extent. The release buttons are then depressed and the barrel portion will be spring ejected from the pistol. It is important that this action only be performed with the barrel portion aimed downwards into a suitable waste container (suitably identified
15 for this type of waste).

It will be understood that various modifications may be made to the embodiment disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of a preferred embodiment. Those skilled in the art will envision other modifications within
20 the scope spirit of the invention.